



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/471,255	12/23/1999	JOSEE HAMEL	55190-012	7195
20277	7590	02/20/2004	EXAMINER	
MCDERMOTT WILL & EMERY 600 13TH STREET, N.W. WASHINGTON, DC 20005-3096			PORTNER, VIRGINIA ALLEN	
			ART UNIT	PAPER NUMBER
			1645	
DATE MAILED: 02/20/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/471,255

Applicant(s)

HAMEL ET AL.

Examiner

Ginny Portner

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 12 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 16, 18-20, 25, 33-35 and 39-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 18 is/are allowed.
- 6) ☐ Claim(s) 16, 19-20, 25, 33-35, 39-42 is/are rejected.
- 7) ☐ Claim(s) 19 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1645

DETAILED ACTION

Claims 16, 18-20, 25, 33-35, 39-42 are pending.

Claims 1-15, 21-24, 26-32, and 36-38 have been canceled.

All claims have been amended or recite a new combination of claim limitations based upon amendment of the independent claims.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Allowable Subject Matter

2. Claim 18 defines over the prior art of record and is therefore allowed.

3. Claims 19 and 20 are objected to as not further limiting the claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, or through incorporation of the claim limitations set forth in claims 19 and 20 into independent claim 18, wherein claims 19 and 20 would then be further limiting of the base claim.

Rejections Withdrawn

4. Claims 16, 18-20, 25, 32-35 and 38-42 objected to because of the following informalities: for reciting non-elected inventions has been obviated through deletion of the non-elected inventions.

5. Claims 16, 18, 25, 32-35 and 38-42 rejected under 35 U.S.C. 112, second paragraph, for reciting the phrase "an amino acid sequence of SEQ ID Nos 2"; for reciting the term "an (claims 32-33)" has been obviated through the deletion of this phrase, and term, respectively, from the claims.

6. Claims 41-42 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention; in light of the deletion of the phrase "second polypeptide" from the claims.

7. Claims 16, 25, 32-35 and 38-42 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, in light of the amendment of the claims to no longer recite "second polypeptide".

8. Claims 25, 34-35, 40 and 42 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the production of a polypeptide consisting of SEQ ID NO 2 and use of the polypeptide for the induction of a protective immune response when combined with QuilA, and immunogenic fragments for the induction of antibodies to detect SEQ ID No 2,

Art Unit: 1645

does not reasonably provide enablement for the use of any polypeptides that only share 95% sequence identity with a second polypeptide that comprises any portion of an amino acid sequence of SEQ ID NO 2 to induce a protective immune response, in light of the amendment of the claims to no longer recite "second polypeptide".

9. Claims 16, 18-20, 25, 32-35 and 38-42 rejected under 35 U.S.C. 102(a) as being anticipated by WO98/18930 has been obviated through amendment of the claims to no longer recite a combination of claim limitations that read in fragments of 447 amino acids out of over 1039 amino acids.

Rejections Maintained

10. Claim 34 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is maintained in part over claim 34, that are directed to polypeptides that evidence less than 100% identity with SEQ ID NO 2, and may or may not have an N-terminal Methionine to start with; thus claim 34 would not be further limiting of these embodiments as claim 34 does not define where or how the claimed polypeptides that are not SEQ ID NO 2 differ from the polypeptide encoded by SEQ ID NO 2.

11. Claim 35 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is maintained in part over claim 35, that are directed to polypeptides that evidence less than 100% identity with SEQ ID NO 2, and may or may not have a secretory amino acid sequence to start with; ; thus claim 35 would not be further limiting of these embodiments as claim 35 does not define where or how the claimed polypeptides that are not SEQ ID NO 2 differ from the polypeptide encoded by SEQ ID NO 2.

Response to Arguments

12. The rejections of claim 34 and 35 under 35 U.S.C. 112, second paragraph for reciting a combination of claim limitations that lack antecedent basis in the independent claim from which they depend, is traversed on the grounds that SEQ ID NO 2 provides inherent antecedent basis for a N-terminal methionine residue and a secretory sequence, and therefore obviates the rejection based upon the newly submitted claim limitations.

13. It is the position of the examiner that while SEQ ID NO 2 does have an N-terminal and secretory amino acid sequence, the claims are not solely limited to SEQ ID NO 2, but to a genus of polypeptides that share less than 100% sequence identity with SEQ ID NO 2, up to about 50 amino acids difference with SEQ ID NO 2, by reciting "at least 95% identity. SEQ ID NO 2 is an amino acid sequence of 1039, and a 5% difference would result in a polypeptide that differs

Art Unit: 1645

13. by about 50 amino acids. Which and where the amino acids that have been deleted, changed or inserted at various locations is not clearly pointed to insure that the independent claim polypeptide provides antecedent basis for both an N-terminal methionine and/or secretory sequence. Amendment of the independent claim could possibly obviate this rejection.

New Claim Limitations/New Grounds of Rejection

Specification

14. The substitute specification filed August 12, 2003 has not been entered because it does not conform to 37 CFR 1.125(b) and (c) because: A marked up copy of the Specification showing changes was not provided.

Claim Objections

15. Claims 19-20 and 34-35 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

16. Claims 19-20 and 34-35 depend from claims 18 and 33, respectively, which have been amended and limited to SEQ ID NO 2; claims 19-20 and 34-35 are directed to molecules that are smaller in size than SEQ ID NO 2, thus broadening the scope of claims 18 and 33 from which they depend. The claim limitations of the dependent claims could be incorporated into the independent claim, and then would be further limiting.

Claim Rejections - 35 USC § 112

17. Claims 16, 25, 33-35, 38-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

18. Claims 16, 25, 33-35, and 38-42 all have been amended to be directed to a polypeptide that is functionally required to elicit a protective immune response through the recitation of either of these phrases “elicits a protective anti-streptococcal immune response in an individual” or “vaccine”. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed. The critical structural characteristic(s) required for the recited functional limitations are not in the claims for polypeptides that are 95% or 99% identical to SEQ ID NO 2; the region that provides critical protective characteristics not recited in the claims for polypeptides that differ from SEQ ID NO 2.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1645

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on 8:30-6:00 M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
February 11, 2004


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1645